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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,746	03/29/2004	Jacob Guth	05408/100M675-US1	5468
7278	7590	09/13/2007		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,746

Applicant(s)

GUTH ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 8/27/07 is acknowledged. Claims 1, 3-10, 14-19 are being considered on the merits.

Claims 11-13 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-10, 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul (U.S. Patent No. 6,149,924) in view Cavazza et al. (EP 0631779), Johnsen (US patent 3,683,939), Vromen (US patent 6,416,759), Yu *et al.* (US patent 5,589,505) and Deckner *et al.* (U.S. Patent No. 5,968,528) for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a topical composition comprising L-carnitine and/or an acyl L-carnitine or their salts and one or more of hydroxy acids, proteolytic enzymes, skin lightening agents as topical preparations having a certain pH.

Paul discloses topical compositions comprising L-carnitine and a hydroxy acid. See, e.g., col. 3 and 6. Glycolic acid is a preferred hydroxy acid (col. 15, line 16).

The reference differs from the invention as claimed in that the pH is not disclosed and in the presence of various components.

However, Cavazza discloses the use of various additives in cosmetic compositions. See, e.g., page 8. In addition, Johnsen discloses that the pH for cosmetics is favorable in the range of 5.5 to 7 (col. 5). In addition, Vromen adequately demonstrates that proteolytic enzymes such as papain are routinely added to cosmetic or topical compositions. See, e.g., col. 2.

With regard to the use of skin bleaching agents, Yu *et al.* adequately demonstrate that it is old in the art to add various materials to cosmetic compositions, such as skin bleaches. See, e.g., col. 2. In addition, Deckner *et al.* teach the specific skin lighteners kojic acid and arbutin (col. 31, lines 40-60). This reference also discloses the use of hydroxy acids such as salicylic,

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glycolic and lactic in topical compositions. See, e.g., col. 31, lines 1-12. Moreover, the use of carnitine in such compositions is disclosed at col. 24, line 22. Deckner teaches that the pH should preferably be between 5 to 8. (Col. 10, line 15.)

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the compositions of Paul containing L-carnitine by using various additives to the cosmetic composition and keeping the pH at between 5.5 and 7 for example, and using various additives such as proteolytic enzymes, bleaches, lighteners, etc. as suggested by the teachings of Cavazza et al., Johnsen, Vromen, Yu et al. and Deckner *et al.* for the expected benefit of providing a topical composition suitable for rejuvenating ageing skin.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention.

While Paul does not disclose a specific pH for the composition, Paul does recognize that a pH of 4-6 is desirable for the topical compositions disclosed. See, e.g., col. 16, lines 30 -35, wherein it is stated:

"Studies have shown that an acidic pH promotes the formation of a competent permeability barrier of the skin than an alkaline pH (Maibach: Cosmetic & Toiletries Magazine, 111: 101-102, 1996). An acidic pH (in the range of 4-6) not only promotes barrier functions, but also fights infection."

Therefore, the Paul reference provides compelling motivation to formulate compositions for topical application to the skin at a pH within the claimed range.

In addition, with regard to Applicant's request for clarification regarding Yu's disclosure of additives to cosmetic compositions, i.e., the "laundry list" disclosed by Yu *et al.*, it is noted

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with all due respect that claim 1 is directed to a variety of purposes as the intended use, potentially requiring a large variety of additives to the material specifically recited therein. In this regard, as noted at page 3 of the office action, skin bleaches, for example, are disclosed in Yu *et al.* at col. 2. Moreover, Applicant argues that the citation of Deckner relies on hindsight to assemble bits and pieces from various laundry lists. However, this is incorrect in that both Yu *et al.* and Deckner *et al.* are relied upon to demonstrate the knowledge in the art rather than to assembling bits and pieces using hindsight as alleged.

Applicant argues that Deckner is in error in attributing thickening properties to carnitine because it is a water soluble quaternary amine. However, there is no clear indication on this record that it cannot act as a thickener in some circumstance, particularly if combined with other substances. In any event, the reference unequivocally suggests providing carnitine in the cosmetic composition in some amount.

Regarding Cavazza, the esters of the reference are at least a form of L-carnitine. This reference is relied upon for the use of various additives in topical compositions for application to the skin.

In response to applicant's comments that Johnsen merely discloses hair care products, it is respectfully noted that hair care products come in contact with skin and are certainly topical (Response, page 8, paragraph 1).

In response to applicant's conclusion that one of the references teach or suggest the pH range of the topical composition of the presently claimed invention, it is emphasized that Paul recognizes that a pH of 4-6, for example, is favorable for composition for skin application, which include, of course, the compositions as claimed comprising (a) at least one compound selected from (i) L-carnitine, (ii) an acyl L-carnitine, (iii) a salt of L-carnitine thereof, and (iv) a salt of an acyl L-carnitine or a mixture thereof and (b) one or more hydroxy acids, proteolytic enzymes, skin lightening agents, or a mixture thereof in undisclosed amounts. Moreover, the adjustment of pH is within the ordinary skill in the skin treating art, particularly whenever enzymes are involved having specific pH preferences or requirements.

Applicant's arguments have failed to rebut the strong *prima facie* case of obviousness made out over the references. Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx
Primary Examiner
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